



September 6, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
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**NATIONAL
FOOD
PROCESSORS
ASSOCIATION**

Re: Docket No. 98N-0359; Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments; 67 Federal Register 42272; June 21, 2002.

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits the following comments on CFSAN priorities for FY 2003. In the above referenced notice, FDA requested comments concerning the establishment of program priorities in CFSAN for FY 2003. Specific comments were requested concerning the establishment of program priorities in CFSAN for its 2003 work plan, the CFSAN 2002 Program Priorities serving as a list of activities for comments to help structure the FY 2003 workplan.

The National Food Processors Association (NFPA) is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

NFPA strongly believes that food safety issues should continue as the number one priority of CFSAN. We do, however, recognize that security of the food supply will continue to be a high priority for FDA, as it is for the food industry. Also we acknowledge that 2002 has been a year of adjusted priorities following the events of September 11, 2001 and that due to increased food security efforts on the part of the Agency, some of the "A" list items from 2002 have not been completed. In those cases, NFPA recommends that CFSAN retain on its 2003 priorities "A" list any items that remain incomplete from the 2002 priorities list. The current enumerated priorities are the most significant items requiring attention and resources at FDA, and having been identified as priorities,

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they should remain on the priority list until completed. Retaining items on the list until completed will also ensure that CFSAN does not undertake work that exceeds its resource allocations. We believe that sufficient progress will be made annually on these priorities and that enough flexibility will remain for CFSAN to accommodate emerging issues.

Assuring Food Safety and Security

Priorities on the “A” list that have not been completed should be retained on the “A” list for 2003 and given priority and resources to be completed.

Strategy 1.1 Food Security: General

FDA faces an extremely challenging task to complete four major new regulations by the end of 2003 under the new bioterrorism act which was signed into law by President Bush. We believe the Act represents a broad expansion of FDA's food-related enforcement authorities, therefore, the Agency will need to be circumspect in how it invests its new resources to assure the most effective food security protections. We recommend that the Agency closely conform to the intent of Congress given the vast scale of the Bioterrorism Act's food provisions and be alert to the potential impact on commerce if not properly implemented.

Strategy 1.2 Domestic Inspections

NFPA recommends FDA incorporate Food Chemicals Codex (FCC) standards/specifications into appropriate sections of 21 CFR.

The specifications and test methods in 21 CFR are frequently out of date. FCC standards are current and revised on an on-going basis. By using the current FCC specifications CFSAN will ensure that the most recent information about food additives and GRAS substances is in its regulations, meaning that those companies following FDA regulations will have the most recent information available to them when preparing purchase specifications. CFSAN funds the work of the FCC, participates in its meetings, and is involved with the development of the monographs on a continuing basis. Once the monographs are finalized, FDA publishes a Federal Register announcement requesting public comment on them. This notice could be modified to include incorporation into the appropriate standard(s) as a part of the process. Following a review of the comments and a final endorsement of the monographs by the National Academies the final monographs could be included in the appropriate standard(s).

Strategy 1.3 Imports and Foreign Inspections

General Comments: NFPA does not disagree with the priorities established relative to import and foreign inspections, noting that a “risk-based” approach is essential to maximize efficient use of FDA resources and to substantiate the need for increased surveillance to our trading partners. NFPA notes that the priorities in this category fail to appropriately reflect related new statutory

requirements established in the bioterrorism law, some of which establish 18-month regulatory requirements. Instead, the goal descriptions appear to reflect the FY 2000 joint FDA/Customs imported food safety initiative. Furthermore, NFPA encourages FDA to work closely with other federal agencies in the process of promulgating guidance and regulations to increase import surveillance and to avoid duplicatory or inconsistent requirements and maximize federal resources in this regard.

- 1.3.1 FDA/U.S. Customs Joint Action Plan: In comments filed October 30, 2002 NFPA suggested FDA work with Customs to facilitate implementation of new statutory regulations for prior notification of food importation. The bioterrorism law implementation time-line suggests finalization of this rule should be “A” priority.
- 1.3.2 Guidance for field personnel for determining which health and safety violations are sufficiently serious. NFPA notes that the bioterrorism legislation refers to “serious adverse health consequences” in relation to food security. NFPA notes the importance defining the “criteria” and clarifying the relationship of the terms to food security and/or food safety, and communicating those definitions in a transparent manner allowing opportunity for comment by all stakeholders.
- 1.3.3. Foreign Inspections: As noted previously, inspections should be risk based and care must be taken to assure that all foreign inspections are in compliance with trade commitments and do not invite retaliation from trading partners.
- 1.3.5 Develop a proposed rule to set standards for the use of private laboratories for testing of imported foods: In March 2000, NFPA submitted comments in response to the Federal Register notice of January 21, 2000 supporting this goal. NFPA believes that, considering the new food security needs as well as those of the imported food safety initiative, it will be imperative to use private laboratories to meet new resource demands. Consequently, these standards should become an “A” priority.

Strategy 1.4 Seafood Safety

Evaluation of FDA’s Seafood Safety program should be a continuing effort to ensure regulatory policy is effective and efficient. NFPA agrees that the process of evaluation should rely heavily on the “state of the industry”, which should not be described primarily by level of regulatory compliance, but rather by performance characterized by the industry’s ability to consistently produce safe products; that is, the characterization should take into consideration specific product safety history, and result in identification of regulatory enforcement and policy priorities focused on products that have a history of higher risk. The effectiveness of this approach is demonstrated by the identification of certain shellfish as a higher risk product, and the allocation of higher priority status to efforts focused on strategies for controlling *Vibrio vulnificus* in raw oysters. Efforts to develop effective control strategies for *Vibrio vulnificus* in raw oysters should remain “A” list priorities for 2003 if adequate strategies have not been developed by the end of FY02. NFPA recommends FDA recognize and accommodate the uniqueness of similar products that

differ in harvest area and process technique to ensure compliance policy and guidance is not misdirected.

As we have not yet seen the report responding to GAO's evaluation of the FDA seafood safety program, we presume this may be a carryover "A" list priority for 2003. FDA should emphasize the safety record for most seafood products, as well as the identification of higher risk products where regulatory efforts should be focused. We understand FDA has developed a more accurate method of classifying compliance with critical elements of the seafood HACCP provisions in 21 CFR 123 (which results in a more accurate and higher level of compliance than that reported by GAO). We are also aware of extensive training efforts undertaken by FDA to ensure consistency among investigators. The consistent safety record for most seafood, identification of higher risk products, more accurate methods used for evaluating compliance, increased training, and the industry's own efforts to ensure that food safety controls have a science-based underpinning should be the key messages conveyed to Congress.

With regard to methyl mercury in commercial seafood, NFPA anticipates this will be elevated to "A" list priority for 2003. NFPA believes the findings of the Food Advisory Committee support the applicability and interpretation of the scientific information that formed the basis for FDA's Consumer Advisory and provides a useful basis for identifying priorities.

Strategy 1.5 Fruits and Vegetables

Juice HACCP should be retained as an "A" priority to address training and compliance issues. Although the final rule was published in January 2001, the Juice HACCP Alliance, coordinated by the National Center for Food Safety and Technology, has only recently completed development of and released the core training curriculum for both FDA and the industry. Moreover, the juice Hazards and Controls Guidance has got to be released as soon as possible.

FDA should elevate Juice HACCP training to an "A" priority for FY 2003 and be prepared to participate in industry training sessions as well as in the training of Federal and State inspection personnel.

Strategy 1.9 Chemical Contaminants, Pesticides and other Hazards

Acrylamide

Swiss, UK and Norwegian researchers have pointed out that acrylamide appears to be formed naturally in foods by some cooking processes. The level in food and the chemistry by which acrylamide is formed in food is not understood and there is little scientific knowledge on its possible effects on human health through consumption of food. NFPA recommends that FDA continue refinement of analytical methods to measure acrylamide levels in foods, explore the mechanism of formation of acrylamide in food and develop data to assess the implications of acrylamide levels in food on public health.

Strategy 1.10 Transmissible Spongiform Encephalopathies (TSE)

Add the following item to the “A” priority list for 2003:

Enhance regulatory presence in evaluating BSE/TSE risk within the U.S. and increase frequency of inspection of animal feed operations to ensure compliance with existing regulations.

Strategy 1.11 Food Allergens

CFSAN should develop more science in the area of food allergies to describe and predict the relationship between foods and human allergenicity, including threshold levels for major food allergens (peanuts, soybeans, milk, eggs, fish, crustaceans, tree nuts, and wheat) that may elicit reactions in sensitive individuals. Acknowledging that CFSAN may not be in a position to undertake the human clinical trials necessary to determine food allergen reaction thresholds, CFSAN should cooperate with other HHS agencies in supporting such clinical research initiatives.

CFSAN should devote resources to develop, either in collaboration with other agencies or by itself, reference allergen standards so commercial allergen test kits can be properly evaluated. The availability of reference allergen standards, which are urgently needed but currently unavailable, allow correlation of analytical results obtained from one commercial kit to another. Currently, the same homogeneous sample analyzed by four different commercial peanut kits yielded four different results.

CFSAN should also set a higher priority in evaluating commercial allergen test methods in foods, starting with peanuts, not only to support FDA’s monitoring program, but to obtain data from illness related consumer complaint incidents for quantitative allergen risk assessment. If the incidents are properly assessed, such data should shed light on the threshold levels of the allergens in real situations.

CFSAN should set criteria for determining how changes should be made to the list of major food allergens that FDA enforces. CFSAN should also harmonize with USDA and State agencies on assignment of recall classifications.

Strategy 1.12 Education

The following item should be added to the “B” list for 2003:

Use funds to distribute the “Food Irradiation: A Safe Measure” information brochure so it is used in teaching and school food safety curricula.

As noted in Section 1.5, we recommend that CFSAN elevate Juice HACCP training to an “A” priority for FY 2003 and be prepared to participate in industry training sessions, as well as in the training of Federal and State inspection personnel.

As a general rule, FDA should ensure that, as new policies and regulations are promulgated, FDA has a well developed educational plan for the affected industries. These would include Q & A’s, workshops, seminars, written implementation materials, web-based presentations, etc.

Assuring Food and Cosmetic Safety: Specific Program Areas

Strategy 2.2 Nutrition, Health Claims and Labeling

1. First Amendment

The Food and Drug Administration (FDA) has announced that the Agency is seeking public comment on whether its regulations and policies on food and drug product labeling and advertising are constitutional. NFPA has a long history of advocacy of First Amendment application to food labeling regulations. NFPA wishes to renew the request it has made to the Agency in prior submissions, that the Agency promptly reopen its consideration of the First Amendment reforms proposed in the 1994 NFPA Citizen Petition (Docket No. 94P-0390). The legal analysis and reforms proposed in the 1994 NFPA petition foreshadowed the *Pearson* decision, and compel FDA to take seriously its obligation to embrace reforms of the specific kind NFPA has proposed. In our 1994 citizen petition, NFPA presented for FDA consideration a broad and concrete proposal for reconstructing the regulations FDA adopted in implementing the health claim and nutrient content claim provisions of the Nutrition Labeling and Education Act of 1990 (NLEA). The 1994 NFPA petition proposed concrete reforms of FDA policy that would go a long way in addressing First Amendment concerns.

While CFSAN has maintained on its priority list for several years an action item to develop a final rule providing for more flexibility in the use of health and nutrient content claims, NFPA notes that such a rule has not yet been made final. Given FDA’s request for comments on First Amendment issues, and the state of the administrative record on the rulemaking docket for NFPA’s 1994 citizen petition, we believe that the appropriate course for CFSAN to undertake in FY 2003 is a rulemaking proceeding that reopens consideration of the 1994 NFPA Citizen Petition and addresses the critical First Amendment issues presented therein.

2. Food Allergen Labeling

With regard to food allergen labeling, NFPA has strongly supported the use of “plain language” on food labels, and has advocated that food allergen labeling options should be flexible and voluntary. NFPA believes that plain language presentation options for food allergens should not replace, but rather should augment, current ingredient labeling requirements. In line with these views, NFPA recommends that FDA add to its “A” list for FY 2003 the objective of developing guidance to industry to accommodate voluntary food allergen labeling that presents plain language names of major food allergens.

3. Revisions to Reference Daily Intakes (RDI) and Daily Reference Values (DRV)

Add the following item to the “B” list for 2003:

Initiate a multi-year strategy to incorporate NAS Dietary Reference Intake (DRI) work into revisions to RDIs and DRVs, for application as Daily Values on nutrition labels. NFPA recognizes that the Dietary Reference Intake report on Electrolytes and Water, and the Food and Nutrition Board (FNB) report on Uses of DRIs in Nutrition Labeling are still pending, and likely will not be completed until FY 2004. Nonetheless, NFPA believes it is as apparent to CFSAN as it is to us that future changes to RDIs and DRVs are likely. NFPA believes it would be appropriate for CFSAN in FY 2003 to initiate strategic planning for any potential labeling changes, including a tentative timetable for rulemaking, so that work may proceed immediately upon delivery of the final reports from the FNB.

4. Prevention of Economic Fraud

CFSAN should make issues related to economic fraud a priority for attention. The Agency must maintain a recognized presence in the area of enforcement to assure that consumers are not being cheated, and that the reputable food industry is not at a disadvantage for complying with the law and regulations. Ensuring consumer confidence in the food supply through prevention of economic fraud is a necessary corollary of consumer protection through strong food safety activities. FDA has an obligation to enforce the existing statutory provisions and to continue to pursue and prosecute fraudulent activities.

Consistent with this view, NFPA believes it is appropriate for FDA to place a higher priority on its work related to food standards of identity. Maintenance of the regulatory framework for food standards is important for both consumers and the food industry, yet FDA has consistently advanced few priorities related to food standards. NFPA believes that FDA has an opportunity to make strong progress on food standards issues by focusing more resources on the development of guiding principles for food standards. Addressing general principles for food standards will facilitate modernization of food standards and updating to reflect advances in technology. This issue has appeared on the CFSAN priority list for several years, yet little progress is apparent. NFPA recommends that FDA promote to an “A” priority for 2003 the current “B*” priority item on developing a proposed rule on guiding principles for standards in collaboration with USDA.

Maintain the following as a “B” priority item for future work if not completed FY 2002:

Develop a final rule to amend FDA regulations for food irradiation labeling.

Strategy 2.3 Dietary Supplements

As proposed in FY 2002, publish final rule on GMPs for dietary supplements in FY 2003. This is important as a prerequisite for those considering voluntary HACCP for production of these products. These should be at least equivalent to the food GMPs to address any safety concerns.

Assuring Food Safety: Crosscutting Areas

Strategy 3.3 – International

Incorporate Food Chemicals Codex (FCC) standards/specifications into appropriate sections of 21 CFR.

Continue the current “A” list priority items into 2003.

(a) Codex Committees and Working Groups. In addition to the listed items that NFPA supports as an “A” priority there is a need to ensure FDA has funding to do extensive outreach before the Codex meetings to educate - especially developing countries - on the issues and the science behind the U.S. positions. This takes funds and resources.

(b) NAFTA TWGs: Actively participate in Technical Working Groups (TWGs) with Canada and Mexico by taking a leadership role on issues of high priority. Passive participation is not enough - the Agency must take a lead role on food initiatives to make more effective use of the TWGs as a venue to address ongoing cross border issues directed towards barriers, policy, procedures, and standards in order to facilitate trade under NAFTA. In addition, TWGs will be created under the Free Trade Area of the Americas (FTAA) Agreement. Used effectively, TWGs can provide excellent forums to harmonize standards, build support for international alliances, reduce trade barriers and prevent trade disruptions.

3.3.3 (a) Export Certificates: Export certificates should be an “A” priority. Significant progress has been made on compilation of data. It is imperative that progress must be made towards elaborating an FDA export certificate that is more responsive to both the needs of importing nations and to food exporters. Discuss and review needs with states, industry, trade agencies, consumer groups and other stakeholders. Assure consistency of international guidance regarding export certificates with U.S. practices.

3.3.4 (b) "Export Certification Procedures" also need to be on the “A” priority list. The US has a positive balance of trade in food products, due primarily to further processed food products (value added food products). The increase in requests from importing countries for official government certification of imported food products threatens to slow or halt this trade. FDA must harmonize U.S. standards with those adopted by Codex in 2001 and continue a leadership role with other Federal and State officials and industry representatives to develop a domestic solution for export certification that will meet importing nations' demands in a timely manner, maximize regulatory resources and facilitate trade.

3.3.5 Equivalence Criteria: FDA developed draft guidance for equivalence criteria and published a notice in the Federal Register in June 1997. In the interim, Codex Alimentarius is nearing completion of guidelines on the determination of criteria. NFPA is supportive of both the work of Codex and the earlier FDA draft guidance and we believe equivalency agreements can be useful to minimize resource needs and facilitate trade. NFPA is also aware that many nations have sought U.S. determinations regarding equivalence of standards. Final rules have not yet been published and CFSAN continues to list this work as a “B” priority. This should be an “A” priority.

Strategy 3.4 – Food Biotechnology

NFPA strongly recommends moving from the “B” list to the “A” list publication of the final rule on mandatory pre-market notification for biotech foods and final guidance for voluntary food labeling of biotech foods.

As a “B” list item, NFPA suggests FDA develop a consumer education program on biotechnology addressing the safety and benefits of foods and ingredients developed through biotechnology and address other issues, which have been identified as consumer concerns.

Strategy 3.6 – Focused, Economic Based Regulations

We suggest that CFSAN review its backlog list of pending petitions to amend standards of identity (especially those associated with temporary marketing permits) and add these to the “B” list for 2003. A timetable should be established to get the requested action underway, with priority for petitions addressing outstanding NLEA issues or products currently packaged under temporary marketing permits.

NFPA requests FDA consider as a “B” priority item for 2003 the 1989 citizens petition (Docket No. 88P-0190/CP02) to amend the canned salmon standard of identity at 21 CFR 161.170. NFPA understands that FDA is currently evaluating their “Guiding Principles for Standards”; however until those principles are developed we feel the appropriate amendments to the canned salmon standard of identity would provide companies the opportunity to introduce innovative new products to the market under the identity standard that would satisfy the preferences of their consumers. Because of the development of new processing technologies and further identification of consumer desires since 1989, NFPA also would like to advise FDA that further amendments to the petition are being considered for submission to FDA prior to 2003.

CFSAN should review and complete these items in a timely manner. If the Agency can initiate and complete a notice detailing labeling requirements for catfish in one year, because of a Congressional mandate, we feel the individual or individuals involved in that activity can certainly be detailed to work on other regulations involving seafood products.

The following “B” list item from 2002 should be upgraded to the “A” list for 2003:

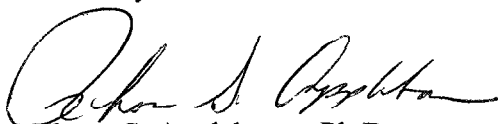
Develop proposed regulations on standard of fill for canned tuna based on the drained weight of the contents, to allow for upgrades in methodology for determining weight and to achieve consistency with international standards.

Conclusion

In conclusion, NFPA appreciates this opportunity to provide comments on the establishment of program priorities for CFSAN for FY 2003.

We understand that CFSAN may need to amend priorities during the year to address emerging situations (as was done in FY 2002) and to implement any new considerations that may be identified as a part of The President's Management Agenda for FY 2003. Likewise, NFPA will communicate to CFSAN any emerging situations that the Association feels require additional attention/resources during the coming year.

Sincerely,

A handwritten signature in black ink, appearing to read "Rhona S. Applebaum". The signature is fluid and cursive, with a large initial "R" and "A".

Rhona S. Applebaum, Ph.D.
Executive Vice President
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NFPA

The Food Safety People

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